

National Vaccine Program
2010 State of the Program Report
February 2011

The National Vaccine Advisory Committee

Executive Summary: 2010 – A renewed focus on prevention

Over the course of 2010, a series of initiatives in the Federal government have refocused public health efforts on the core concept of prevention. These include the passage of health care reform with prevention provisions and the revision and publication of the goals for the Healthy People initiative. The National Vaccine Program Office (NVPO) continued work on updating the National Vaccine Plan to guide national vaccine policy. The National Vaccine Advisory Committee has been involved in efforts to ensure that vaccine safety is critically addressed, and the completion of the H1N1 influenza vaccination campaign, there have been a number of advances in vaccination policy and practice.

Many of these efforts are still in their nascent stages. Regulations for implementing the Patient Protection and Affordable Care Act are continually being developed and revised following public and stakeholder input. The new Healthy People 2020 goals were first launched in December 2010, and evaluation of progress and barriers by the NVAC will be an ongoing process. Examinations of the H1N1 influenza pandemic and associated vaccination campaign are underway through a number of forums. Two initiatives which address vaccination practice and policy as partial components, the National Prevention Strategy and the work of the Interagency Viral Hepatitis Working Group, are currently being developed and implemented.

Other efforts are still being fully defined. The NVAC Vaccine Safety Working Group is conducting a review of the vaccine safety system; the final strategic National Vaccine Plan is nearing completion, but will require the development of an implementation plan by NVPO. The recommendation for annual influenza vaccination of all Americans that was recently made will need to be evaluated as we move forward, a task charged to the NVAC. Recognizing the advances in vaccination coverage for children, and to a certain extent, adolescents, efforts are underway by the NVAC Adult Immunization Working Group to identify recommendations to develop a robust adult immunization program.

Overall, the National Vaccine Program has functioned well in both reactive and proactive manners, and increases in coordination that were achieved during the H1N1 influenza pandemic appear to be a stepping stone to greater coordination throughout the entire Program. The focus on increased coordination has been a central component of recent NVAC work, and will continue to be an area of focus moving forward.

Recent Activities Impacting the National Vaccine Program

The Impact of Health Care Reform

The passage of the Affordable Care Act (ACA), in addition to providing millions of Americans who previously had no health care coverage, put in place requirements to increase the use of preventive services. This is most clearly seen by the section calling for all new health care plans, and plans that have lost their grandfathered status, to cover all recommended preventive services, including Advisory Committee on Immunization Practices (ACIP)-recommended vaccinations, without cost-sharing. In 2010, the NVAC provided input, in the form of a reiteration of prior NVAC recommendations, to a call for public comment on the development of regulations for the implementation of the ACA.

In addition to removing financial barriers to preventive services, the ACA calls for research into systems and processes to improve vaccination uptake, as well as indefinitely authorizing the Section 317 grant program, which provides funds for immunization system infrastructure and vaccine purchase to state and local grantees.

While there will be time until all components of the ACA will be implemented, many of the barriers to effective and widespread immunization coverage have been addressed by the law.

Looking Back at H1N1 Influenza and Forward to Seasonal Influenza

The public health response to the H1N1 influenza pandemic that began in early 2009 provided the framework for many improvements in the nation's immunization system. First, there was a renewed focus on the need for influenza vaccination with wider awareness of circulating influenza virus. Second, the public health response that enrolled more than 72,000 providers to receive and administer H1N1 influenza vaccine (<http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-oct09/12-5-flu-vac.pdf>) encouraged many health care providers who had not previously provided influenza vaccine to begin immunization programs in their practices. Third, the rapid development and deployment of new vaccine safety monitoring systems and the inclusion of a transparent vaccine safety monitoring program, through the NVAC H1N1 Vaccine Safety Risk Assessment Working Group, allowed for an unprecedented review of the safety of a vaccine during a wide-scale immunization campaign. The NVAC participated in a review of the H1N1 response conducted by the RAND Corporation, on behalf of the Office of the Assistant Secretary for Preparedness and Response.

Building off of lessons learned from the confusion of influenza vaccination recommendations that differed in target populations for the seasonal influenza vaccine and the H1N1 influenza vaccine, and the need to generally increase influenza vaccine uptake, the ACIP recommended that all Americans aged 6 months and older be vaccinated against influenza annually. The Assistant Secretary for Health, in response to these changed recommendations, has asked the NVAC to evaluate the uptake of seasonal influenza vaccine in this first year of the universal vaccination recommendation.

The infrastructure developments that were made to respond to the pandemic, including newly enrolled providers, a centralized vaccine order and distribution system, and vaccination uptake monitoring provide a model framework for improvements in the overall vaccination infrastructure. However, with uncertainties regarding long-term funding, and the ending of time-limited funding through the American Recovery and Reinvestment Act and the Public Health Emergency Response grants, these infrastructure developments are in danger of being lost, which would impact not just planning for a future pandemic but also the general immunization programs already in place.

Roadmaps for Health – The National Vaccine Plan and Healthy People 2020

The release of the new Healthy People 2020 goals on December 2, 2010 provide health planners with updated targets for improvements in all aspects of American's health. Newly defined objectives to address adolescent and adult immunization have increased the scope of the Healthy People immunization and infectious disease section. The NVAC has been asked by the Assistant Secretary for Health to review

not only the progress made towards achieving the Healthy People 2020 goals, but also to review and comment on the barriers that exist to reaching these goals.

The increased coordination and detailed goals for the National Vaccine Program outlined in the updated National Vaccine Plan should help with reaching the Healthy People 2020 goals. While the National Vaccine Plan update was not released in 2010, the ongoing work in the National Vaccine Program Office is moving the Plan towards release in early 2011.

Vaccine Safety – Making a Good System Better

The widespread use of vaccines to prevent disease is well-known. However, the systems in place to address possible adverse outcomes of disease are not well known. While the system has historically functioned well, the NVAC Vaccine Safety Working Group has been asked to review the overall system, and recommend ways to make a good system better. This effort has broadened the way that prevention is viewed with regard to vaccines, by not only preventing disease through vaccines, but by focusing on preventing adverse effects of vaccines. This process began in July 2009, after a review of the Centers for Disease Control and Prevention Immunization Safety Office scientific agenda, and is ongoing, with a final report and recommendations anticipated in 2011.

Vaccinations across the Lifespan – The Importance of Adult Immunization

During the H1N1 influenza pandemic, the efforts to immunize populations not typically targeted for influenza vaccination, including young adults, highlighted the difficulties in disease prevention across the lifespan. While pediatric and adolescent vaccination uptake levels are at or near all-time high levels, adult vaccination levels are typically much farther behind. After a review of Federal adult immunization programs that was completed in 2009, the NVAC Adult Immunization Working Group began examining the wider range of issues and barriers to increased adult immunization rates. This effort is ongoing, and the final report and recommendations are expected in 2011. Additionally, in 2010, the Assistant Secretary for Health asked the National Vaccine Advisory Committee to examine the role of racial and ethnic disparities in influenza immunization coverage, a task that has been incorporated into the work of the NVAC Adult Immunization Working Group.

Increased emphasis on coordination

Through the current work of the NVAC working groups, the efforts of the Interagency Vaccine Group (IAVG) and the Federal Immunization Safety Task Force (ISTF), which are coordinated through the National Vaccine Program Office, and the efforts to address the H1N1 influenza pandemic, a consistent theme of continued coordination of efforts has emerged. It is anticipated that upcoming NVAC Working Group reports and recommendations will call for strengthening the role of these coordination functions.

NVAC Recommendation

In advance of these upcoming recommendations, the NVAC makes the following recommendation. All recommendations of the NVAC are made to the Department's Assistant Secretary for Health. Thus, this recommendation will be formally transmitted to the Assistant Secretary for Health, who will review and consider it for potential implementation options to include communications with various components of the Department.

RESOLVED: The Secretary of Health and Human Services should strengthen the role of the Interagency Vaccine Group and the Federal Immunization Safety Task Force, including the designation of subcommittees to address specific topics, to increase the level of coordination among Federal agencies involved in the National Vaccine Program, and to increase the effectiveness of the activities currently underway by the components of the National Vaccine Program.

National Vaccine Program Goals for 2011

Building off of the activities conducted throughout the National Vaccine Program in 2010, there are a number of goals identified for the coming year. A summary of recent charges and goals for the NVAC is present in Appendix 3. For 2011, the following goals have been identified:

- Release of the Strategic National Vaccine Plan in February 2011, with ongoing development of the associated implementation plan by NVPO
- NVAC Adult Immunization Working Group white paper and recommendations completed and presented to the NVAC by June 2011;
- NVAC Vaccine Safety Working Group white paper and recommendations completed and presented to the NVAC by September 2011;
- Continued progress of the NVAC Adult Immunization Working Group Healthcare Personnel Influenza Vaccination Subgroup;
- Ongoing NVAC review of the barriers to achieve Healthy People 2020 goals;
- Completed examination of the uptake of influenza vaccine in the first year of the universal influenza vaccination recommendation by the NVAC;

Appendix 1. Statutory charge to the National Vaccine Program and National Vaccine Advisory Committee

The National Vaccine Program (NVP), National Vaccine Program Office (NVPO), and National Vaccine Advisory Committee (NVAC) were created in 1986 as part of the National Childhood Vaccine Injury Act of 1986. The relevant Federal statutes governing these entities are found in 42 USC 300aa-1 – 300aa-6, which correspond to Title XXI of the Public Health Service Act (P.L. 99-660), sections 2101-2106. Section 2104 was repealed as part of the Federal Reports Elimination Act of 1998 (P.L. 105-362).

Roles and responsibilities of the NVP and the NVAC

The Director of the NVP is the Assistant Secretary for Health, United States Department of Health and Human Services (DHHS). As outlined in Section 2102 of Title XXI of the Public Health Service Act, there are nine responsibilities assigned to the Director of the NVP:

- (a) Vaccine research – coordinate and provide direction for research carried out in or through the National Institutes of Health (NIH), the Centers for Disease Control (CDC), the Office of Biologics Research and Review of the Food and Drug Administration (OBRR), the Department of Defense (DoD), and the Agency for International Development (AID) on means to introduce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.
- (b) Vaccine development – coordinate and provide direction for activities carried out in or through the NIH, OBRR, DoD, and AID to develop the techniques needed to produce safe and effective vaccines.
- (c) Safety and efficacy testing of vaccines – coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the NIH, CDC, OBRR, DoD and AID.
- (d) Licensing of vaccine manufacturers and vaccines – coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 353.
- (e) Production and procurement of vaccines – ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, DoD, and AID meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.
- (f) Distribution and use of vaccines – coordinate and provide direction to the CDC and assistance to the States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and make health practitioners and the public aware of potential adverse reactions and contradictions to vaccines.
- (g) Evaluating the need for, and the effectiveness, adverse effects of vaccines and immunization activities – coordinate and provide direction to the NIH, CDC, OBRR, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effective and adverse effects of vaccines and immunization activities.
- (h) Coordinating governmental and non-governmental activities – provide for the exchange of information between Federal agencies involved in the implementation of the Program and the non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental funding activities under the Program.

- (i) Funding of Federal agencies – shall make available to Federal agencies funds appropriated under section 2106 to supplement the funds otherwise available to such agencies for activities under the Plan.

The NVAC provides recommendations to the Director of the NVP within four defined responsibility areas. As outlined in Section 2105 of Title XXI of the Public Health Service Act, NVAC shall:

- (a) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States
- (b) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines
- (c) advise the Director of the Program in the implementation of sections 2102 and 2103 of Title XXI of the Public Health Service Act
- (d) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 2102 and 2103 of Title XXI of the Public Health Service Act.

Appendix 2. Summary of Recent National Vaccine Advisory Committee and National Vaccine Program Office Activities

NVAC Vaccine Safety Working Group

Overview and recently completed actions

The Vaccine Safety Working Group (VSWG) was formed in April 2008, and began working to address its first charge, a review of the CDC Immunization Safety Office Scientific Agenda. A report on this review, with associated recommendations was approved by the NVAC in June 2009. In July 2009, the VSWG moved forward with its second charge – a review of the entire Federal vaccine safety system.

Current actions

Throughout 2010, the VSWG, and its associated subgroups, performed an extensive information gathering to better understand the workings of the vaccine safety system. Throughout this process, opportunities for improvement were identified and a series of recommendations to address these opportunities were drafted. The VSWG is continuing to meet to further refine its report and recommendations.

A preliminary presentation from the CDC ISO on the implementation of steps to address the NVAC VSWG Charge 1 recommendations was given to the NVAC in June 2010.

Future steps

It is anticipated that throughout 2011, the VSWG process will continue, with additional refinement of its report and recommendations, gathering stakeholder input on the report, with a goal of a final presentation of the report to the NVAC in September 2011 for deliberation and potential vote for Committee approval.

Additional reports from CDC ISO on efforts to implement their scientific agenda, with the associated NVAC recommendations, are anticipated moving forward.

NVAC H1N1 Vaccine Safety Risk Assessment Working Group

Overview and recently completed actions

Following the initial plans for an H1N1 influenza vaccination campaign, the NVAC adopted a series of recommendations addressing ways in which vaccine safety should be monitored. One recommendation, calling for external, independent, transparent review of H1N1 influenza vaccine safety was implemented by the creation of the H1N1 Vaccine Safety Risk Assessment Working Group (VSRAWG). Starting in December 2009, the VSRAWG met regularly, receiving reports of vaccine safety-related data from a variety of reporting sources.

Current actions

The VSRAWG presented their findings to the NVAC through both regularly scheduled NVAC in-person meetings as well as off-schedule public meeting teleconferences. Weak signals identified through the VSRAWG review were followed up.

Future steps

The VSRAWG is currently completing its end-of-season analysis and review, which is expected to be presented to the NVAC in early 2011.

NVAC Adult Immunization Working Group

Overview and recently completed actions

The Adult Immunization Working Group (AIWG) was formed in 2008. Through 2008 and the first half of 2009, the AIWG reviewed Federal adult immunization programs, and provided a report and recommendations to the NVAC which were approved by the Committee in June 2009. After adoption of this report, the AIWG moved on to address its second charge, a wider review of adult immunization in the US.

Current actions

Throughout 2010, the AIWG performed an exhaustive review of prior adult immunization recommendations to identify what has been achieved and what still remains to be achieved. These outstanding gaps formed the basis for targeted recommendations which are being finalized.

Additionally, the National Vaccine Program Office tasked the NVAC with reviewing ways to improve influenza vaccination rates among healthcare personnel. This task was taken on by the AIWG, which created a Health Care Personnel Influenza Vaccination Subgroup. Initial organizational meetings of this subgroup were held at the end of 2010.

Future steps

The broad AIWG will continue to develop its report and recommendations through the first half of 2011, including the gathering of stakeholder input. It is anticipated that the final report and recommendations will be presented to the NVAC for Committee deliberation and vote in June 2011.

The Health Care Personnel Influenza Vaccination Subgroup will be focused on information gathering efforts in the early part of 2011. The timeline for the Subgroup is still under development.

NVPO – National Vaccine Plan

Overview and recently completed actions

For the past three years, NVPO has coordinated a cross-departmental effort to update the 1994 National Vaccine Plan. The 2010 National Vaccine Plan was also developed with input from NVAC, the public, and vaccine stakeholders. It includes strategies on all aspects of the vaccine enterprise, including research and development, supply and financing, distribution, safety, communications, disease surveillance, and global cooperation. The 2010 National Vaccine Plan went into clearance at HHS, USAID, the VA, and the Department of State in December 2010.

Current actions

NVPO is working to address comments received during clearance and finalize the Plan for printing. Launch and stakeholder engagement plans are currently being made. The 2010 National Vaccine Plan will be publicly released at the February 16-17, 2011, NVAC meeting.

Future steps

NVPO will work with national, regional, and local stakeholder groups to receive input on the priority areas in the 2010 National Vaccine Plan and begin developing implementation plans beginning in Spring 2011. The 2010 National Vaccine Plan will be reviewed annually by NVPO and NVAC, with a formal mid-course review in 2015.

NVPO – Communications

Overview and recently completed actions

During 2010 NVPO organized and led a cross-Department effort to develop a consolidated website of vaccine-related information targeted at the general public. This site was developed as a result of focus group research to understand beliefs, perceptions, and concerns with pediatric immunization. Many of the participants in these focus groups were supportive of immunization but nearly all had questions about vaccines they felt were not adequately being answered by their health care providers, online resources, other media, or their peers. From these focus groups stemmed the idea for a single online resource that provides a complete portrait of vaccine issues from development to licensure to administration.

The website will be a consumer portal that draws information from across the department and is based on the model pioneered by Flu.gov. Understanding that women are often the primary health information seekers for their families—and may make health decisions for young children, teenagers, or aging parents—women and mothers age 25-55 will be an initial primary target audience. The site will present information to reflect the importance of immunization across the lifespan from children to seniors, with a particular focus on orienting consumers toward the benefits of vaccines and reestablishing social norms around immunization.

Current actions

The website is in the final stages of usability testing and is anticipated to be “live” in early Spring 2011.

Future steps

NVPO will work with a cross-Department steering group to continually update content.

Appendix 3. Summary of Recent Charges to National Vaccine Advisory Committee and Goals for 2011

General Description	Charge to NVAC / Goal	Points of Contact / Responsible Parties	Deliverables	Timeline
National Vaccine Plan	Continuous monitoring of implementation of National Vaccine Plan	Mark Grabowsky / NVPO Sarah Landry / NVPO NVAC	NVAC will receive updates on the implementation of the National Vaccine Plan	Ongoing
Healthy People 2020	Identify barriers, suggest solutions and monitor progress towards the new Healthy People 2020 goals for the nation	Sarah Landry / NVPO NVAC	NVAC will provide ongoing process of an annual review of barriers to achieving HP2020 goals	Ongoing
Vaccine Safety	Completion of Vaccine Safety Working Group report	Dan Salmon / NVPO NVAC Vaccine Safety. WG	Report and recommendations	Final report anticipated September 2011
Adult Immunization	Completion of Adult Immunization Working Group report	Mark Grabowsky / NVPO NVAC Adult Imm. WG	Report and recommendations	Final report anticipated June 2011
Health Disparities	Reduction and elimination of health disparities, particularly as they related to influenza vaccination of adults	Ray Strikas / NVPO NVAC Adult Imm. WG	Health disparities are being addressed by the Adult Immunization WG, and recommendations on this topic will be included in the larger white paper and recommendations	Conclusion of Adult Immunization Working Group white paper process, anticipated June 2011
Healthcare Worker Influenza Vaccination	Develop recommendations related to improving health care worker influenza vaccination rates	Mark Grabowsky / NVPO NVAC Adult Imm. WG Health Care Personnel Influenza Vaccination Subgroup	Recommendations	Final report anticipated September 2011

General Description	Charge to NVAC / Goal	Points of Contact / Responsible Parties	Deliverables	Timeline
Universal Influenza Recommendation	Review the performance of the influenza vaccination program in the first year of a universal recommendation	Mark Grabowsky / NVPO Ray Strikas / NVPO NVAC	Evaluation report following conclusion of influenza season	Discussions in September and February NVAC meetings
Hepatitis	Review and comment on materials coming from Inter-Agency Viral Hepatitis WG	Ray Strikas / NVPO NVAC	NVAC as a whole will review and provide comment on materials when they are made available	As materials become available